Report M 053

Relationships Between Rupture Rates and Surgical and Product Parameters From Mentor's Adjunct Clinical Study

August 2004

In an attempt to further characterize modes and causes of rupture for Mentor's silicone gel-filled breast implants, a statistical analysis of the relationships between rupture rate and parameters associated with device implantation, as well as device characteristics, was undertaken using data derived from the Adjunct Clinical Study database. For the purposes of this analysis, only ruptures that occurred after the date of implant surgery, *i.e.*, ruptures that occurred in devices that were implanted without apparent damage were considered. Out of --------- implanted devices recorded in the database, only 159 met this definition of failure. A detailed description of the statistical analyses of the data is presented in Attachment I.

The following populations were analyzed:

(1) Total population (TP) of the Adjunct Study database

  (2) Smooth devices within the TP

  (3) Textured devices within the TP

(4) Revision Augmentation Subpopulation (RAS) of the total Adjunct database population

  (5) Smooth devices within the RAS

  (6) Textured devices within the RAS

(7) Total Reconstruction Subpopulation.

The following parameters were assessed:

- Surgical approach
  - □ Inframammary
  - □ Transaxillary
  - □ Periareolar
- Device placement
  - □ Subglandular
  - □ Submuscular
- Incision size
  - □ Small (3 cm)
  - □ Medium (3-6 cm)

- Large (6-9 cm)

- Device size (150-800 cc)
- Interaction of device size and incision size
- Surface characteristic (smooth versus textured)

Since the rates of device rupture in the Adjunct Study were very low, the parameter for analysis (rupture rate, "RR") was defined as the rate of rupture per 10,000 implant years. Relationships between RR and the factors listed above were analyzed using Poisson regression methods. A complete discussion of the statistical methodology employed, and the factors considered in deriving the relationships, is provided in the full study report

The results of this analysis are summarized below and in Table 1.

- Device placement has a statistically significant influence on rupture rates, with submuscular placement being associated with a 2–3.3-fold higher rupture rate than subglandular placement, in populations (1), (3), (4) and (6) above. Device placement appears not to influence rupture rate for smooth devices (any indication) or devices implanted for reconstruction.

  Submuscular placement can provide greater cyclic stress on a device as the muscle contracts and relaxes. Probably of greater significance in producing failures is the fact that the device is more closely confined in the submuscular position. This makes folding and wrinkling of the device more likely. This folding exacerbates cyclic fatigue that can lead to failures classified as localized shell fatigue failures. Textured devices are more prone to this mode of fatigue failure due to their thicker shells. Thickness of shells is a direct determinant of the stress applied to the surface of the shell on the outside of the shell; the thicker the shell the greater the stress. Conversely, smooth devices have thinner shells and are less susceptible, but not immune, from this type of failure. Thus, the higher rupture rate seen with submuscular implantation of textured devices is not an unexpected finding.

- Smooth implants tend to have 1.5–1.8-times higher rupture rates than textured devices (except in the reconstruction subpopulation).

  When the question is asked whether textured or smooth devices fail with the greatest frequency as a result of device placement, the answer is textured devices, as explained in the above response. However, when the broader question is asked as to which type of device fails in general after implantation, the answer is just the opposite. In general, smooth devices fail more frequently. This apparent dichotomy can be easily reconciled. The graphs and statistics in the Mentor report on modes and causes of gel implant failures show that there is an elevated frequency of failure of devices intraoperatively and in the 0-1 and 1-2 year time intervals for both the "Rupture-Unknown Cause" (RUC) and "Not Apparent-

Etiology Unknown" (NAEU) populations of failed gel-filled devices. Further, comparison of the plots for total population of failures to those for thin line failures of the shell for each of the two (RUC and NAEU) populations separately, reveals that thin line shell failures account for essentially all failures in those time intervals. See the table below for those comparisons.

	Failures in Different Time Intervals			A: Total Failures from 0 to 2 years	B: Total Population of Failures	Ratio of A to B
Failure Populations	**Intraoperative Failures (Time =0)**	**0-1 years**	**1-2 Years**			
Rupture-Unknown Cause (RUC)	31	3	13	47	121	
Thin Line Shell-RUC	30	2	10	42		35%
Not Apparent-Etiology Unknown (NAEU)	3	13	6	22	45	
Thin Line Shell-NAEU	3	13	6	22		49%

The thin line shell device failures in the 0 to 2 years period for the RUC and NAEU populations account for 35% and 49% of the total failures in those populations, respectively. These failures are a large potion of each of the respective populations.

In the Mentor report on modes and causes of failures (Report M 053), it is postulated that the failures during the 0 to 2 year timeframe result from damage to the devices during implantation. These thin line failures will most likely result from instrument damage (scalpel nicks or needle punctures) or localized stress that weakens the shell in a small area. Smooth devices have thinner shells than textured devices, because the texturing process adds an additional layer to the device. A rough estimate of the thickness of thin shells is 0.010 to 0.012 inches; for textured devices this measurement is approximately 0.018 to 0.020 inches. The thinner shells of the smooth devices may be more susceptible to localized stress damage, i. e., thinner sections of any elastomer require less stress to elongate the elastomer to its ultimate elongation. Also, it is logical that any sharp instrument damage that is done to a thinner shell may propagate to a larger opening in less time than with a thicker shell.

Thus, we see that the underlying mechanism governing the frequency of failures for textured devices over smooth ones when only placement is considered, and that the mechanisms responsible for the failure of devices with smooth shells over those with textured surfaces in the overall populations are different and understood.

- Surgical approach has no influence on rupture rate for all populations and subpopulations.

  This result is not surprising. Where the incision is made on the breast to insert an implant should be of little consequence on the stress that is applied to the device to place it into the surgical pocket. Any stress would be more dependent upon the surgical technique than the location of the incision on the breast.

- An analysis was performed to determine if size of device (volume) had an influence on frequency of rupture. For this analysis devices were categorized into the following categories:

Category	Device Size (cc)
1	<= 300
2	> 300 and <= 375
3	> 375 and <= 500
4	> 500

  First, the rates of rupture were compared across these four categories. If statistical significance was found, then the categories were compared pairwise. The results of this analysis are summarized below:

- Total Adjunct Study population

  - Statistically significant difference (p = 0.025) across all categories

  - Statistically significant difference between categories 1 and 4 (p = 0.05) and 2 and 4 (p = 0.02). The ratio of rupture rate for categories 4 to 1 is 1.7 and that for 4 to 2 is 2.1.

- Textured Devices in Adjunct Study population

  - There is a weak statistically significant difference when all categories of textured device sizes are compared (p = 0.054).

  - There is a statistically significant difference between categories 2 and 3 and 2 and 4. The ratio of rupture rates for categories 3 to 2 is 1.9, and for 4 to 2 the ratio is 2.6.

- There is no statistically significant difference across the device size categories for (1) the total Revision Augmentation subpopulation or the Total Reconstruction Subpopulation, (2) smooth devices in the Adjunct Study population or in the Revision Augmentation subpopulation or (3) textured devices in the Revision Augmentation subpopulation.

- An analysis of the Total Reconstruction Subpopulation was done. No statistically significant results were obtained. Within this subpopulation, the numbers of implant-years of exposure to textured and smooth devices were, when viewed separately, too small to perform a meaningful statistical analysis on them.

The above results indicate that there is a higher failure rate for larger devices, but the trend is not strong. In most cases, the difference in rates can only be established for non-adjacent categories of implants, e. g., when the <300 cc or >300 to <=375 cc categories are compared to >500 cc devices. This may indicate that the limitation of incision size imposed for the sake of aesthetics is of a marginal size to accommodate larger size devices. Another contributing factor is likely to be that larger devices may have a greater tendency to fold or wrinkle. Folding and wrinkling can contribute to cyclic fatigue failure in those areas. It should be emphasized that the tendency of larger size devices to fail is weak and hard to detect.

- Incision size has no influence on rupture rate for all populations and subpopulations.

  At first blush, this result seems surprising. Logic dictates that, for a given size of incision, one would expect that, as the volume of an implant increases, more stress would be required in the implantation procedure, more damage would be done to the implant shell and, consequently, a higher frequency of failures would result. The key phrase is "for a given size of incision." Surgeons are apparently making the logical adjustment, i. e., with larger implants they are making larger incisions. If this is true, then the relationship of incision size to implant volume remains in a range that results in no correlation between incision size and frequency of failure across all populations and subpopulations.

  A more detailed analysis was performed in which the influences of both device size and incision size on frequency of failures were considered, in a factorial ANOVA-like manner. The analysis was aimed at determining if these two factors interact; i. e., whether the RR changed differently, with respect to increasing device size, for different incision sizes. The results of this analysis are:

  Regardless of the population or subpopulation, there is no interaction between device size and incision size in influencing the RR. Thus, although RR does increase slightly with increasing device size, the increase seems to be the same for all the incision sizes. One cautionary note: the power of this test for interaction is not as high as that for the one-factor tests, so it is possible that a subtle interaction has been missed in this analysis.

The mechanisms for failure as proposed in the Mentor report on modes and causes of failure in gel-filled devices provide credible explanations for the trends that were identified by this statistical analysis of the Adjunct Clinical Study database. The total number of postoperative failures (159) identified in the Adjunct database was small in comparison to the total number of individual devices ---------- included in the database. The small numbers of implant-years of exposure and of failed devices prevented reliable analyses of some subpopulations for the effects of certain parameters on rupture rates. This was especially true in the Total Reconstruction Subpopulation.

TABLE 1
SUMMARY OF RELATIONSHIPS BETWEEN RUPTURE RATES AND SURGICAL AND PRODUCT PARAMETERS FROM MENTOR'S ADJUNCT STUDY

	Surgical Approach	**Device Placement**	**Device Size**	**Incision Size**	**Device Size + Incision Size**	**Surface Characteristic (Smooth vs. Textured)**
Total Population[a] (TP)	NS[b]	*p=0.0008* (all categories) *p=0.000019* (subglandular vs. submuscular; rupture rate for submuscular placement is 2.09 times greater than subglandular placement	*p=0.02* across all categories *p=0.05 and 017* for devices >500 cc compared to ≤300 cc and devices 500 cc compared to 300-375 cc, respectively	NS	The rupture rate as device size increases is not influenced by incision size.	*p=0.049* rupture rate for smooth is 1.50 times greater than textured)
Smooth (TP)	NS	NS	NS	NS	The rupture rate as device size increases is not influenced by incision size.	
Textured (TP)	NS	*p=0.000028* (subglandular vs. submuscular; rupture rate for submuscular placement is 2.42 times greater than subglandular placement)	Nearly significant difference (p = 0.054) across all categories *p=0.04 and 0.015* for devices 300-375 cc compared to 375-500 and devices 300-375 compared to>500	NS	The rupture rate as device size increases is not influenced by incision size.	

	Surgical Approach	Device Placement	Device Size	Incision Size	Device Size + Incision Size	Surface Characteristic (Smooth vs. Textured)
			cc, respectively			
Revision Augmentation Subpopulation[a] (RAS)	NS	*p=0.0003* (subglandular vs. submuscular; rupture rate for submuscular placement is 2.39 times greater than subglandular placement)	NS	NS	NS	*p=0.04* (rupture rate for smooth is 1.84 times greater than textured)
Smooth (RAS)	NS	NS	NS	NS		
Textured (RAS)	NS	*p=0.0002* (subglandular vs. submuscular; rupture rate for submuscular placement is 3.28 times greater than subglandular placement)	NS	NS		
Total Reconstruction Subpopulation	NS	NS	NS	NS		NS

[a]Includes both smooth and textured devices

[b]Not statistically significant

Gray shading indicates that either the analysis was not relevant, e. g., surface characteristic analysis in a subpopulation of either smooth or textured device, or that the implant-years of exposure for a population were so small that the analysis would not be meaningful.

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ATTACHMENT I

RELATIONSHIPS BETWEEN RUPTURE RATES AND SURGICAL AND PRODUCT PARAMETERS FROM MENTOR'S ADJUNCT STUDY

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1. Introduction

1.1 *Purpose*

The purpose of this report is to provide information concerning the relationships between implant device failure and factors attendant to device implantation procedure (e.g., surgical parameters) and device structure (e.g., size, surface characteristics).

1.2 *Data*

The data used for this report were derived from the Adjunct Clinical Study database, a database set up to record contact information between implant patients and their doctors over the course of their participation in the study. The database contains records of implant surgeries with dates, surgical parameters and implant details (e.g., one versus two implants, side of body), and also the dates and descriptions of any resulting ruptures.

It is important to know that the data collected emanates from the participating doctors. No arrangement for unbiased data collectors was made in the study.

Since this report focuses on device rupture, a precise definition of "rupture" – as the term is used here – is needed. First, although it occasionally happens that a device ruptures during the implant surgery, such rupture events are NOT included in this report. More specifically, a device "rupture" is taken here to mean that the device was implanted without apparent damage to it, but then ruptured on a date strictly AFTER its implant date. Table 1.2 makes this distinction clear: this report uses the 159 ruptures in the third row of the table.

Table 2.1. Ruptures Used in this Report

Device Classification	Count
All Devices Implanted	----------
All Ruptured Devices	179
Devices Ruptured AFTER implant date	159

1.3 *Statistical Methodology*

Since the term "rupture," as it is used here, refers to an implant-level event (and not merely a patient-level or surgery-level event), the first step in the statistical analysis was to convert the surgery-level records in the original database to implant-level records. As such, the derived database used here contains one record for each implant, with the attendant information (implant surgery date, surgical parameters, type and size of the implanted device, rupture date if any) included.

From the implant surgery date and the rupture date (given that a rupture occurred), one can derive the time until failure for the implant. For implants which had not ruptured by the date (6/24/2004) of the database retrieval, one can derive the current "time on test".

Of course, there are several potential ways of analyzing the relationships between the occurrence of the "rupture" event and other factors:

(a) Analyze the distribution of the "time until failure", using survival analysis methods such as Kaplan-Meier or the Cox proportional hazards model.
(b) Analyze the probability of a rupture, using logistic regression
(c) Analyze the rate of rupture per unit of implant (in vivo) exposure, using Poisson regression.

For this report, we dismissed methods (a) and (b), and adopted method (c), for the following reasons.

First, we dismissed method (a) since, as will be seen, over 99% of the implants had not ruptured by the retrieval date of the database, and hence would have provided only censored information in an analysis of time until failure. It is well-known that Kaplan-Meier or the Cox models do not work well in the presence of such a high rate of censoring.

Second, although method (b) is technically feasible, its use would require the inclusion of time of (in vivo) exposure of the implants as a factor in all analyses of the effects of other factors. Otherwise, one risks the omission of an important confounder. To keep the analyses presented here as simple as possible – which is important due to their voluminous number – it was decided to dismiss (b) in favor of method (c).

Method (c), which analyzes the rate of rupture per unit of implant exposure, incorporates exposure time into the parameter being analyzed. The natural exposure unit is the "implant year," defined as the condition of ONE implant being in vivo for ONE year. In ensuing tables, the reader will confront exposures of, for example, 100,000 implant years, which can be interpreted as: 100,000 implants in vivo for one year each, or as 50,000 implants in vivo for two years each, and so on.

Since the rates of rupture of the devices studied here are so low, to make the numbers convenient to report and interpret we have adopted "10,000 implant years" as the standard exposure unit. Correspondingly, we have defined "the rate of ruptures per 10,000 implant years," henceforth denoted by "RR", as our parameter for analysis throughout this report.

The primary mode of operation in the report is to produce estimates of RR for various disjoint subgroups (defined by the factors under study) of the data, along with the corresponding standard errors. These estimates are then compared across the subgroups.

There are, of course, several methods of obtaining these estimates, all of which are loosely termed "Poisson regression." One aspect of the present database that presents difficulties in trying to analyze data from it is that there are often (due to multiple implants, or even multiple implant surgeries, per patient) multiple implant records per patient. For the purpose of estimating RR, such "clustered" data are commonly analyzed via the generalized estimating equation (GEE) methodology, which seeks to obtain proper standard errors in the presence of within-patient correlation, without losing too much statistical efficiency (due to avoiding full likelihood specification).

For the present database, which contains upward of --------- implant records, the implementation of the GEE methodology provided by SAS's PROC GENMOD took an exorbitant time to execute. (Note: SAS stands for the "Statistical Analysis System" software package.) However, it was discovered that the GEE standard error estimates differed from those under assumed "independence within patients" only in the third or fourth decimal place. As such, it seemed reasonable – and prudent – to ignore the within-patient association (which is apparently weak) and analyze the data assuming independence of implant rupture responses within patients. The estimation method employed here, therefore, is to simply use the maximum likelihood estimator (mle) of RR in a given subgroup, along with its usual standard error. To be explicit, let E denote the total exposure (in units of 10,000 implant years) of implants in a given subgroup, S. Let R denote the total ruptures in S. Assume that R has a Poisson distribution with mean = E x RR. Then the mle of RR for subgroup S is

$$RR^\wedge = R / E,$$

with standard error

$$se(RR^\wedge) = R / E2.$$

Furthermore, by standard asymptotic theory for the Poisson distribution, the estimate RR^ has an approximate normal distribution when E is large. Thus, standard methods (e.g. Wald statistics) of comparing the RR values in disjoint subgroups can be – and are here – utilized. Alpha=.05 is taken to be the criterion of statistical significance throughout.

Finally, we remind the reader that this data arises from an observational (i.e., non-randomized) study, so the usual caution – vis-à-vis confounders -- should be exercised in interpreting the results. More specifically, using data of this nature, one can never rule out the possibility that a significant difference in RR -- shown here to be due to a difference in some surgical- or device-related conditions – is due to some confounder, and not to the alleged difference in conditions.

2. Results in the Total Study Population

2.1. Rate of Ruptures vs. Surgical Approach in the Total Population

The Adjunct Study database distinguishes five surgical approaches for making an implant:

Inframammary
Transaxillary
Periareolar
Scar
Other

Table 2.1. shows the estimates of rate of rupture per 10,000 implant years (henceforth RR), by surgical approach.

Table 2.1. Rate of Rupture (RR) per 10,000 Implant Years in the Total Population, By **Surgical Approach**

Approach	Total Implant Years	Total Ruptures	RR	std. err.
Inframammary	285,180.7	76	2.66	0.31
Periareolar	159,992.3	41	2.56	0.40
Scar	5,422.1	1	1.84	1.84
Transaxillary	15,328.4	4	2.61	1.30
Other	91,049.4	32	3.51	0.62
Missing	8,043.8	5	6.22	2.80

Note: There is no significant difference in RR across the Surgical Approaches (p=0.61)

2.2. *Rate of Ruptures vs. Device Placement in the Total Population*

The Adjunct Study database distinguishes three device placements for making an implant:

Sub-glandular
Sub-muscular
Other

Table 2.2 shows the estimates of rate of rupture per 10,000 implant years (henceforth RR), by device placement.

Table 2.2. Rate of Rupture (RR) per 10,000 Implant Years in the Total Population, By **Device Placement**

Placement	Total Implant Years	Total Ruptures	RR	std. err.
Sub-glandular	232,808.6	39	1.68	0.27
Sub-muscular	317,246.1	111	3.50	0.33
Other	5,914.7	4	6.76	3.38
Missing	9047.4	5	5.53	2.47

Note: There is a significant difference in RR across all categories (p=.00008). Also, the difference between Sub-glandular and Sub-muscular is significant ($p=1.9 \times 10^{-5}$). The estimate of the ratio RR(Musc)/RR(Gland) is 2.09 (se=0.39).

2.3. *Rate of Ruptures vs. Incision Size in the Total Population*

The Adjunct Study database distinguishes four incision sizes:

Small (0-3 cm)
Medium (3-6 cm)
Large (6-9 cm)
Extra Large (> 9 cm)

Table 2.3 shows the estimates of rate of rupture per 10,000 implant years (henceforth RR), by incision size.

Table 2.3. Rate of Rupture (RR) per 10,000 Implant Years in the Total Population, By **Incision Size**

Incision Size	Total Implant Years	Total Ruptures	RR	std. err.
Small (0-3 cm)	70,520.0	17	2.41	0.58
Medium (3-6 cm)	377,261.8	106	2.81	0.27
Large (6-9 cm)	108,155.0	35	3.24	0.55
Extra Large (>9 cm)	529.3	0	0.00	0.00
Missing	8550.6	1	1.17	1.17

Note: There is no significant difference in RR across the Incision Sizes (p=.90). Size Categories 'Extra Large' and 'Missing' were omitted from the significance test due to their low representation in terms of implant years.

2.4. *Rate of Ruptures vs. Device Size in the Total Population*

The size (volume in cubic centimeters) of the implanted devices vary from 150-800. The median and upper and lower quartiles of the device size distributions for the Smooth and Textured devices are given in Table 2.4.1.

Table 2.4.1. Selected Quantiles of the Device Size Distribution in the Total Population, for Smooth and Textured Devices

Device Type Quantile	Smooth	Textured
25th	300	275
50^{th}	375	350
75^{th}	500	450

From this table, one sees that the Smooth devices in the study tend to be slightly larger than the Textured devices. To keep the ensuing analysis simple similar to that in previous sections, we create four device size categories as follows:

Category 1: device size <= 300
Category 2: > 300 device size <= 375
Category 3: > 375 device size <= 500
Category 4: device size > 500.

Thus, category j corresponds exactly to the jth quarter of the Smooth device size distribution, and approximately to the jth quarter of the Textured device size distribution. All analyses regarding device size will be done using these device size categories.

Table 2.4.2 shows the estimates of rate of rupture per 10,000 implant years by device size category. There are statistically significant (p=.025) differences across all the categories in the table, and across all categories, omitting the "Missing" category (p=.059). Table 2.4.3 shows the results of pairwise comparison of the non-missing categories, from which the primary finding is that size category 4 (> 500 cc) devices have a significantly higher RR than the smaller devices.

Table 2.4.2. Rate of Rupture (RR) per 10,000 Implant Years in the Total Population, by **Device Size Category**

Device Size Category	Total Implant Years	Total Ruptures	RR	std. err.
1: <= 300 cc	178,112.5	42	2.36	0.36
2: 300 – 375 cc	128,783.9	25	1.94	0.39
3: 375 – 500 cc	133,689.6	41	3.07	0.48
4: > 500 cc	64,284.2	26	4.04	0.79
Missing	60,146.6	25	4.16	0.83

Note: There are significant (p=.025) differences in RR across these categories. See Table 2.4.3 for pair wise comparisons of the categories.

Table 2.4.3. Pairwise-comparison of Rate of Rupture (RR) per 10,000 Implant Years, in the total Population, **Across Device Size Categories**

Category Comparison	p-value	Rate Ratio[a]	Std. Err.
1 - 2	.43	1.00[b]	-----
1 - 3	.24	1.00	-----
1 - 4	.05	0.58	0.15
2 - 3	.07	1.00	-----
2 - 4	.017	0.48	0.13
3 - 4	.29	1.00	-----

Note: a. The rate ratio for row "1-2" is RR(1)/RR(2), using figures from Table 2.4.2. Standard errors are by the delta method.

b. The Rate Ratio is reported as 1.00 when the hypothesis of equal rates is not rejected.

2.5. *Rate of Rupture by Combinations of Device Size and Incision Size, in the Total Population*

Table 2.5 shows the estimates of rate 1.00of rupture per 10,000 implant years by combinations of device size category and incision size. Due to low representation in terms of implant years, the Incision size categories "Extra large" and "Missing" are omitted from the table.

Table 2.5. Rate of Rupture (RR) per 10,000 Implant Years in the Total Population, by **Device Size Category and Incision Size**

Device Size Category	Incision Size	Total Imp. Years	Total Ruptures	RR	Std. Err.
1: <= 300 cc	Small	23,432.6	6	2.56	1.05
	Medium	118,864.3	24	2.02	0.41
	Large	35,566.0	12	3.37	0.97
2: 300 – 375 cc	Small	15,450.7	1	0.65	0.65
	Medium	91,203.7	19	2.08	0.48
	Large	22,017.4	5	2.27	1.01
3: 375 – 500 cc	Small	16,310.3	4	2.45	1.23
	Medium	93,270.0	28	3.00	0.57
	Large	24,021.4	9	3.75	1.25
4: > 500 cc	Small	7,272.0	3	4.12	2.38
	Medium	42,323.8	16	3.78	0.95
	Large	14,653.8	7	4.78	1.81
Missing	Small	8,054.3	3	3.72	2.15
	Medium	40,150.7	20	4.98	1.11
	Large	11,896.5	2	1.68	1.19

Note: Including the 'Missing" device size category, the hypothesis of no device type X incision size interaction was not rejected (p=.41). Excluding the 'Missing' device size.

The purpose of doing this analysis is to determine if device size and incision size interact in influencing RR. In other words, we want to determine whether increasing the size of the device results in the same change in RR, regardless of the size of incision used, or if perhaps the change in RR is larger for some incision sizes than for others. For example, one might suspect that RR might increase more due to increased device size with small incisions than with larger incisions.

The results (excluding the "Missing" Device Size category) in Table 2.5 indicate – via the acceptance of the no-interaction hypothesis – that the effects on RR of increased Device size seem to be the same, regardless of Incision size.

2.6. Rate of Ruptures vs. Surface Characteristic (Smooth or Textured) in the Total Population

Table 2.6 shows the estimates of rate of rupture per 10,000 implant years by Surface Characteristic.

Table 2.6. Rate of Rupture (RR) per 10,000 Implant Years in the Total Population, By **Surface Characteristic**

Surface Characteristic	Total Implant Years	Total Ruptures	RR	std. err.
Smooth	111,750.2	41	3.67	0.57
Textured	432,799.3	106	2.45	0.24
Missing	20,467.2	12	5.86	1.69

Note: There is a significant difference in RR across the three categories (p= .024). Also, there is a significant difference in RR between Smooth and Textured devices (p=.049). The estimated ratio, RR(Smooth)/RR(Textured) is 1.50 (s.e.= 0.28).

3. Results by Surface Characteristics: Smooth vs. Textured, in the Total Population

3.1. Results for the Smooth Device in the Total Population

3.1.1. Rate of Ruptures vs. Surgical Approach for the Smooth Device in the Total Population

Table 3.1.1 shows the estimates of rate of rupture per 10,000 implant years for the smooth device by surgical approach.

Table 3.1.1. Rate of Rupture (RR) per 10,000 Implant Years for the Smooth Device in the Total Population, by **Surgical Approach**

Approach	Total Implant Years	Total Ruptures	RR	std. err.
Inframammary	51,801.3	19	3.67	0.84
Periareolar	35,850.1	13	3.62	1.01
Scar	3,835.4	0	0.00	0.00
Transaxillary	3,281.7	1	3.05	3.05
Other	15,572.2	7	4.50	1.70
Missing	1,409.5	1	7.09	7.09

Note: There is no significant difference in RR across the Surgical Approaches (p=0.89). Approach categories 'Scar', 'Transaxillary' and 'Missing' were excluded from the significance test due to low representation in terms of implant years.

3.1.2. Rate of Ruptures vs. Device Placement for the Smooth Device in the Total Population

Table 3.1.2 shows the estimates of rate of rupture per 10,000 implant years for the Smooth device, by device placement.

Table 3.1.2. Rate of Rupture (RR) per 10,000 Implant Years for the Smooth Device in the Total Population, by **Device Placement**

Total Placement	Total Implant Years	Ruptures	RR	std. err.
Sub-glandular	33,980.8	9	2.65	0.88
Sub-muscular	75,578.6	30	3.97	0.72
Other	1,014.5	0	0.00	0.00
Missing	1,176.3	2	17.00	12.02

Note: There is no significant difference (p=.25) in RR between sub-glandular and sub-muscular placement.

3.1.3. Rate of Ruptures vs. Incision Size for the Smooth Device in the Total Population

Table 3.1.3 shows the estimates of rate of rupture per 10,000 implant years for the Smooth device, by incision size.

Table 3.1.3. Rate of Rupture (RR) per 10,000 Implant Years for the Smooth Device in the Total Population, by **Incision Size**

Incision Size	Total Implant Years	Total Ruptures	RR	std. err.
Small (0-3 cm)	16,352.2	7	4.28	1.62
Medium (3-6 cm)	76,262.2	25	3.28	0.66
Large (6-9 cm)	16,918.9	9	5.32	1.77
Extra Large (>9 m)	169.7	0	0.00	0.00
Missing	2,047.2	0	0.00	0.00

Note: There is no significant difference in RR across the Incision Sizes (p=.51). Size Categories 'Extra Large' and 'Missing" were omitted from the significance test due to their low representation in terms of implant years.

3.1.4. Rate of Ruptures vs. Device Size for the Smooth Device in the Total Population

Table 3.1.4 shows the estimates of rate of rupture per 10,000 implant years for the Smooth device, by device size category.

Table 3.1.4. Rate of Rupture (RR) per 10,000 Implant Years for Smooth Device in the Total Population, by **Device Size Category**

Device Size Category	Total Implant Years	Total Ruptures	RR	std. err.
1: <= 300 cc	29,055.7	6	2.07	0.84
2: 300 – 375 cc	24,651.7	10	4.06	1.28
3: 375 – 500 cc	32,608.7	13	3.99	1.11
4: > 500 cc	16,422.6	8	4.87	1.72
Missing	9,011.7	4	4.43	2.21

Note: There is no significant difference in RR across the Device Size categories (p=.41).

3.1.5. Results for Rate of Rupture by Combination of Device Size and Incision Size, for the Smooth Device in the Total Population

Table 3.1.5 shows, for the smooth device, the estimates of rate of rupture per 10,000 implant years by combinations of device size category and incision size. Due to low representation in terms of implant years, the Incision size categories "Extra large" and "Missing" are omitted from the table.

Table 3.1.5. Rate of Rupture (RR) per 10,000 Implant Years for the Smooth Device in the Total Population, by **Device Size Category and Incision Size**

Device Size Category	Incision Size	Total Imp. Years	Total Ruptures	RR	Std. Err.
1: <= 300 cc	Small	4,518.9	3	6.64	3.83
	Medium	19,481.1	1	0.51	0.51
	Large	4,962.3	2	4.03	2.85
2: 300 – 375 cc	Small	3,548.2	0	0.00	0.00
	Medium	17,327.5	8	4.62	1.63
	Large	3,741.7	2	5.35	3.78
3: 375 – 500 cc	Small	4,980.9	2	4.02	2.84
	Medium	22,736.2	7	3.08	1.16
	Large	4,864.4	4	8.22	4.11
4: > 500 cc	Small	1,949.2	1	5.13	5.13
	Medium	12,001.4	6	5.00	2.04
	Large	2,457.2	1	4.07	4.07
Missing	Small	1,355.1	1	7.38	7.38
	Medium	6,763.2	3	4.44	2.56
	Large	893.4	0	0.00	0.00

Note: Including the 'Missing" device size category, the hypothesis of no device type X incision size interaction was rejected (p=.04). Excluding the 'Missing' device size category gives a non-significant result (p=.17) for this hypothesis.

The purpose of doing this analysis is to determine if device size and incision size interact in influencing RR. In other words, we want to determine whether increasing the size of the device results in the same change in RR, regardless of the size of incision used, or if perhaps the change in RR is larger for some incision sizes than for others. For example, one might suspect that RR might increase more due to increased device size with small incisions than with larger incisions.

The results (excluding the "Missing" Device Size category) in Table 3.1.5 indicate – via the acceptance of the no-interaction hypothesis – that the effects on RR of increased Device size seem to be the same, regardless of Incision size.

3.2. Results for the Textured Device in the Total Population

3.2.1. Rate of Ruptures vs. Surgical Approach for the Textured Device in the Total Population

Table 3.2.1 shows the estimates of rate of rupture per 10,000 implant years for the textured device by surgical approach.

Table 3.2.1. Rate of Rupture (RR) per 10,000 Implant Years for the Textured Device in the Total Population, by **Surgical Approach**

Approach	Total Implant Years	Total Ruptures	RR	std. err.
Inframammary	224,712.0	51	2.27	0.32
Periareolar	118,801.2	26	2.19	0.43
Scar	1,402.4	1	7.13	7.13
Transaxillary	11,560.8	3	2.59	1.50
Other	71,680.2	23	3.21	0.67
Missing	4,642.7	2	4.31	3.05

Note: There is no significant difference in RR across the Surgical Approaches (p=0.60). Approach categories 'Scar' and 'Missing' were excluded from the significance test due to low representation in terms of implant years.

3.2.2. Rate of Ruptures vs. Device Placement for the Textured Device in the Total Population

Table 3.2.2 shows the estimates of rate of rupture per 10,000 implant years for the Textured device, by device placement.

Table 3.2.2. Rate of Rupture (RR) per 10,000 Implant Years for the Textured Device in the Total Population, by **Device Placement**

Placement	Total Implant Years	Total Ruptures	RR	std. err.
Sub-glandular	191,454.4	26	1.36	0.27
Sub-muscular	230,840.8	76	3.29	0.38
Other	4,671.8	3	6.42	3.71
Missing	5,832.3	1	1.71	1.71

Note: There is a significant difference in RR across all categories (p=.0003). There is also a significant difference between RR for sub-glandular and sub-muscular placement ($p=2.8\times10^{-5}$). The estimated ratio: RR(Musc)/RR(Gland) is 2.42 (se = 0.55).

3.2.3. Rate of Ruptures vs. Incision Size for the Textured Device in the Total Population

Table 3.2.3 shows the estimates of rate of rupture per 10,000 implant years for the Textured device, by incision size.

Table 3.2.3. Rate of Rupture (RR) per 10,000 Implant Years for the Textured Device in the Total Population, by **Incision Size**

Incision Size	Total Implant Years	Total Ruptures	RR	std. err.
Small (0-3 cm)	50,775.2	9	1.77	0.59
Medium (3-6 cm)	288,338.8	70	2.43	0.29
Large (6-9 cm)	87,461.7	26	2.97	0.58
Extra Large (>9 cm)	314.6	0	0.00	0.00
Missing	5909.0	1	1.69	1.69

Note: There is no significant difference in RR across the Incision Sizes (p=.35). Size categories 'Extra Large' and 'Missing" were omitted from the significance test due to their low representation in terms of implant years.

3.2.4. Rate of Ruptures vs. Device Size for the Textured Device in the Total Population

Table 3.2.4 shows the estimates of rate of rupture per 10,000 implant years for the Textured device, by device size category.

Table 3.2.4. Rate of Rupture (RR) per 10,000 Implant Years for Textured Device in the Total Population, by **Device Size Category**

Device Size Category	Total Implant Years	Total Ruptures	RR	std. err.
1: <= 300 cc	149,056.8	36	2.42	0.40
2: 300 – 375 cc	104,132.2	15	1.44	0.37
3: 375 – 500 cc	101,081.0	28	2.77	0.52
4: > 500 cc	47,861.6	18	3.76	0.89
Missing	30,667.7	9	2.93	0.98

Note: There is a nearly significant difference in RR across the Device Size categories (p=.054). See Table 3.2.4b for pairwise comparisons.

Table 3.2.4b. Pairwise-comparison of Rate of Rupture (RR) per 10,000 Implant Years, **Across Device Size Categories**, for the Textured Device in the Total Population

Category Comparison	p-value	Rate Ratio[a]	Std. Err.
1 - 2	.08	1.00[b]	------
1 – 3	.59	1.00	------
1 – 4	.17	1.00	-----
2 – 3	.04	0.52	0.16
2 – 4	.015	0.38	0.13
3 - 4	.34	1.00	------

Note: a. The rate ratio for row "1-2" is RR(1)/RR(2), using figures from Table 3.2.4. Standard errors are by the delta method.

b. The Rate Ratio is reported as 1.00 when the hypothesis

The primary finding from Table 3.2.4b is that Size category 2 (300 – 375 cc) devices seem to have a lower RR than devices from categories 3 and 4.

3.2.5. Results for Rate of Rupture by Combination of Device Size and Incision Size, for the Textured Device in the Total Population

Table 3.2.5 shows, for the textured device, the estimates of rate of rupture per 10,000 implant years by combinations of device size category and incision size. Due to low representation in terms of implant years, the Incision size categories "Extra large" and "Missing" are omitted from the table. The results show no interaction between Device Size and Incision Size.

Table 3.2.5. Rate of Rupture (RR) per 10,000 Implant Years for the Textured Device in the Total Population, by **Device Size Category and Incision Size**

Device Size Category	Incision Size	Total Imp. Years	Total Ruptures	RR	Std. Err.
1: <= 300 cc	Small	18,913.7	3	1.59	0.92
	Medium	99,383.2	23	2.31	0.48
	Large	30,603.7	10	3.27	1.03
2: 300 – 375 cc	Small	11,902.5	1	0.84	0.84
	Medium	73,876.2	11	1.49	0.45
	Large	18,275.7	3	1.64	0.95
3: 375 – 500 cc	Small	11,329.4	2	1.77	1.25
	Medium	70,533.8	21	2.98	0.65
	Large	19,157.0	5	2.61	1.17
4: > 500 cc	Small	5,322.9	2	3.76	2.66
	Medium	30,322.4	10	3.30	1.04
	Large	12,196.6	6	4.92	2.01
Missing	Small	3,306.7	1	3.02	3.02
	Medium	20,132.3	6	2.98	1.22
	Large	7,228.7	2	2.77	1.96

Note: Including the 'Missing" device size category, the hypothesis of no device type X incision size interaction was not rejected (p=.99). Excluding the 'Missing' device size gives the same result (p=.98).

The purpose of doing this analysis is to determine if device size and incision size interact in influencing RR. In other words, we want to determine whether increasing the size of the device results in the same change in RR, regardless of the size of incision used, or if perhaps the change in RR is larger for some incision sizes than for others. For example, one might suspect that RR might increase more due to increased device size with small incisions than with larger incisions.

The results (excluding the "Missing" Device Size category) in Table 3.2.5 indicate – via the acceptance of the no-interaction hypothesis – that the effects on RR of increased Device size seem to be the same, regardless of Incision size.

4. Results for the Revision Augmentation Sub-population

4.1. Rate of Ruptures vs. Surgical Approach in Revision Augmentation Subpopulation

Table 4.1 shows the estimates of RR by surgical approach in the Revision Augmentation (R/A) subpopulation.

Table 4.1. Rate of Rupture (RR) per 10,000 Implant Years in R/A Subpopulation by **Surgical Approach**

Approach	Total Implant Years	Total Ruptures	RR	std. err.
Inframammary	192,984.7	49	2.54	0.36
Periareolar	101,035.3	27	2.67	0.51
Scar	135.5	0	0.00	0.00
Transaxillary	5,998.4	2	3.33	2.36
Other	12,216.4	1	0.81	0.81
Missing	2,676.2	1	3.74	3.74

Note: Omitting the 'Scar', 'Other' and 'missing' levels due to low total implant years, there is no significant difference in RR across the remaining Surgical Approaches (p=0.93).

4.2. Rate of Ruptures vs. Device Placement in the R/A Subpopulation

Table 4.2 shows the estimates of rate of rupture per 10,000 implant years, by device placement, in the R/A subpopulation.

Table 4.2. Rate of Rupture (RR) per 10,000 Implant Years in the R/A Subpopulation, by **Device Placement**

Placement	Total Implant Years	Total Ruptures	RR	std. err.
Sub-glandular	165,349.4	25	1.51	0.30
Sub-muscular	143,928.6	52	3.61	0.50
Other	1,581.1	1	6.32	6.32
Missing	4,187.6	2	4.78	3.38

Note: There is a significant difference in RR across all categories (p=.003). Also, the difference between Sub-glandular and Sub-muscular is significant (p=.0003). The estimated ratio: RR(Musc)/RR(Gland) is 2.39 (se=0.58).

4.3. Rate of Ruptures vs. Incision Size in the R/A Subpopulation

Table 4.3 shows the estimates of rate of rupture per 10,000 implant years, by incision size, in the R/A subpopulation.

Table 4.3. Rate of Rupture (RR) per 10,000 Implant Years in the R/A Subpopulation, by **Incision Size**

Incision Size	Total Implant Years	Total Ruptures	RR	std. err.
Small (0-3 cm)	45,816.8	12	2.62	0.76
Medium (3-6 cm)	221,191.0	55	2.49	0.34
Large (6-9 cm)	43,752.1	13	2.97	0.82
Extra Large (>9 cm)	169.4	0	0.00	0.00
Missing	4,117.3	0	0.00	0.00

Note: There is no significant difference in RR across the Incision Sizes (p=.86). Size Categories 'Extra Large' and 'Missing' were omitted from the significance test due to their low representation in terms of implant years.

4.4. Rate of Ruptures vs. Device Size in the R/A Subpopulation

Table 4.4 shows results for device size in the R/A subpopulation.

Table 4.4. Rate of Rupture (RR) per 10,000 Implant Years in the R/A Subpopulation, by **Device Size Category**

Device Size Category	Total Implant Years	Total Ruptures	RR	std. err.
1: <= 300 cc	106,835.2	22	2.06	0.44
2: 300 – 375 cc	74,879.9	14	1.87	0.50
3: 375 – 500 cc	70,994.4	18	2.54	0.60
4: > 500 cc	30,707.6	12	3.91	1.13
Missing	31,629.4	14	4.43	1.19

Note: There are no significant differences in RR across these categories (p=.17). If the 'Missing' category is excluded, then p=.37.

4.5. Rate of Rupture by Combinations of Device Size and Incision Size, for the R/A Subpopulation

Table 4.5 shows the estimates of rate of rupture per 10,000 implant years by combinations of device size category and incision size. Due to low representation in terms of implant years, the Incision size categories "Extra large" and "Missing" are omitted from the table.

Table 4.5. Rate of Rupture (RR) per 10,000 Implant Years for the R/A Subpopulation, by **Device Size Category and Incision Size**

Device Size Category	Incision Size	Total Imp. Years	Total Ruptures	RR	Std. Err.
1: <= 300 cc	Small	14,438.8	3	2.08	1.20
	Medium	75,297.8	14	1.86	0.50
	Large	16,997.2	5	2.94	1.32
2: 300 – 375 cc	Small	9,912.4	1	1.01	1.01
	Medium	54,908.3	11	2.00	0.60
	Large	10,036.5	2	1.99	1.41
3: 375 – 500 cc	Small	10,946.9	3	2.74	1.58
	Medium	51,220.2	11	2.15	0.65
	Large	8,798.3	4	4.55	2.27
4: > 500 cc	Small	4,950.7	3	6.06	3.50
	Medium	21,733.9	8	3.68	1.30
	Large	4,015.2	1	2.49	2.49
Missing	Small	5,568.0	2	3.59	2.54
	Medium	22,148.1	11	4.97	1.50
	Large	3,904.9	1	2.56	2.56

Note: Including the 'Missing' device size category, the hypothesis of no device type X incision size interaction was not rejected (p=.90). Including the 'Missing' device size category gives the same conclusion (p=.87).

The purpose of doing this analysis is to determine if device size and incision size interact in influencing RR. In other words, we want to determine whether increasing the size of the device results in the same change in RR, regardless of the size of incision used, or if perhaps the change in RR is larger for some incision sizes than for others. For example, one might suspect that RR might increase more due to increased device size with small incisions than with larger incisions.

The results (excluding the "Missing" Device Size category) in Table 4.5 indicate – via the acceptance of the no-interaction hypothesis – that the effects on RR of increased Device size seem to be the same, regardless of Incision size.

4.6. Rate of Ruptures vs. Surface Characteristics (Smooth or Textured) in the R/A Subpopulation

Table 4.6 shows the estimates of rate of rupture per 10,000 implant years by Surface Characteristics, for the R/A subpopulation.

Table 4.6. Rate of Rupture (RR) per 10,000 Implant Years in the R/A Subpopulation, by **Surface Characteristics**

Surface Characteristics	Total Implant Years	Total Ruptures	RR	std. err.
Smooth	61,910.5	23	3.72	0.77
Textured	242,915.1	49	2.02	0.29
Missing	10,221.0	8	7.83	2.77

Note: There is a significant difference in RR across the three categories (p= .016). Also, there is a significant difference in RR between Smooth and Textured devices (p=.04). The estimated ratio: RR(Smooth)/RR(Textured) is 1.84 (se=0.47).

5. RESULTS BY SURFACE CHARACTERISTICS: SMOOTH VS. TEXTURED, IN THE R/A SUBPOPULATION

5.1. Results for the Smooth Device in the R/A Subpopulation

5.1.1. Rate of Ruptures vs. Surgical Approach for the Smooth Device in the R/A Subpopulation

Table 5.1.1. Rate of Rupture (RR) per 10,000 Implant Years for the Smooth Device in the R/A Subpopulation, by **Surgical Approach**

Approach	Total Implant Years	Total Ruptures	RR	std. err.
Inframammary	36,351.0	14	3.85	1.03
Periareolar	21,076.7	8	3.80	1.34
Scar	89.4	0	0.00	0.00
Transaxillary	1,180.5	1	8.47	8.47
Other	2646.2	0	0.00	0.00
Missing	566.8	0	0.00	0.00

Note: Only Inframammary and Periareolar levels were compared, finding no significant difference in RR (p=.97).

5.1.2. Rate of Ruptures vs. Device Placement for the Smooth Device in the R/A Subpopulation

Table 5.1.2 shows the estimates of rate of rupture per 10,000 implant years for the Smooth device, by device placement.

Table 5.1.2. Rate of Rupture (RR) per 10,000 Implant Years for the Smooth Device in the R/A Subpopulation, by **Device Placement**

Placement	Total Implant Years	Total Ruptures	RR	std. err.
Sub-glandular	24,388.8	7	2.87	1.08
Sub-muscular	36,516.1	15	4.11	1.06
Other	283.8	0	0.00	0.00
Missing	721.8	1	13.85	13.85

Note: There is no significant difference (p=.41) in RR between sub-glandular and sub-muscular placement.

5.1.3. Rate of Ruptures vs. Incision Size for the Smooth Device in the R/A Subpopulation

Table 5.1.3 shows the estimates of rate of rupture per 10,000 implant years for the Smooth device, by incision size.

Table 5.1.3. Rate of Rupture (RR) per 10,000 Implant Years for the Smooth Device in the R/A Subpopulation, by **Incision Size**

Incision Size	Total Implant Years	Total Ruptures	RR	std. err.
Small (0-3 cm)	11,044.6	5	4.53	2.02
Medium (3-6 cm)	43,167.3	14	3.24	0.87
Large (6-9 cm)	6,504.9	4	6.15	3.07
Extra Large (>9 cm)	61.0	0	0.00	0.00
Missing	1,132.7	0	0.00	0.00

Note: There is no significant difference in RR across the Incision Sizes (p=.59). Size Categories ‘Extra Large’ and ‘Missing” were omitted from the significance test due to their low representation in terms of implant years.

5.1.4. Rate of Ruptures vs. Device Size for the Smooth Device in the R/A Subpopulation

Table 5.1.4 shows the estimates of rate of rupture per 10,000 implant years for the Smooth device, by device size category.

Table 5.1.4. Rate of Rupture (RR) per 10,000 Implant Years for Smooth Device in the R/A Subpopulation, by **Device Size Category**

Device Size Category	Total Implant Years	Total Ruptures	RR	std. err.
1: <= 300 cc	16,066.5	3	1.87	1.08
2: 300 – 375 cc	13,715.6	5	3.65	1.63
3: 375 – 500 cc	17,640.5	8	4.54	1.60
4: > 500 cc	8,636.5	3	3.47	2.01
Missing	5,851.4	4	6.84	3.41

Note: There is no significant difference in RR across the Device Size categories (p=.49).

5.2. Results for the Textured Device in the R/A Subpopulation

5.2.1. Rate of Ruptures vs. Surgical Approach for the Textured Device in the R/A Subpopulation

Table 5.2.1 shows the estimates of rate of rupture per 10,000 implant years for the smooth device by surgical approach.

Table 5.2.1. Rate of Rupture (RR) per 10,000 Implant Years for the Textured Device in the R/A Subpopulation, by **Surgical Approach**

Approach	Total Implant Years	Total Ruptures	RR	std. err.
Inframammary	151,105.8	30	1.99	0.36
Periareolar	76,455.7	17	2.22	0.54
Scar	36.6	0	0.00	0.00
Transaxillary	4,637.6	1	2.16	2.16
Other	9,303.3	1	1.07	1.07
Missing	1,376.1	0	0.00	0.00

Note: There is no significant difference in RR across the Surgical Approaches (p=.82). Approach categories 'Scar' and 'Missing' were excluded from the significance test due to low implant years.

5.2.2. Rate of Ruptures vs. Device Placement for the Textured Device in the R/A Subpopulation

Table 5.2.2 shows the estimates of rate of rupture per 10,000 implant years for the Textured device, by device placement.

Table 5.2.2. Rate of Rupture (RR) per 10,000 Implant Years for the Textured Device in the R/A Subpopulation, by **Device Placement**

Placement	Total Implant Years	Total Ruptures	RR	std. err.
Sub-glandular	135,698.4	14	1.03	0.28
Sub-muscular	103,288.5	35	3.39	0.57
Other	1,244.6	0	0.00	0.00
Missing	2,683.6	0	0.00	0.00

Note: There is a significant difference in RR for sub-glandular and sub-muscular placement (p=.0002). The estimated ratio: RR(Musc)/RR(Gland) is 3.28 (se = 1.04).

5.2.3. Rate of Ruptures vs. Incision Size for the Textured Device in the R/A Subpopulation

Table 5.2.3 shows the estimates of rate of rupture per 10,000 implant years for the textured device, by Incision Size.

Table 5.2.3. Rate of Rupture (RR) per 10,000 Implant Years for the Textured Device in the R/A Subpopulation, by **Incision Size**

Incision Size	Total Implant Years	Total Ruptures	RR	std. err.
Small (0-3 cm)	32,413.0	6	1.85	0.76
Medium (3-6 cm)	171,561.2	34	1.98	0.34
Large (6-9 cm)	36,084.8	9	2.49	0.83
Extra Large (>9 cm)	99.9	0	0.00	0.00
Missing	2,756.2	0	0.00	0.00

Note: There is no significant difference in RR across the Incision Sizes (p=.82). Size categories 'Extra Large' and 'Missing" were omitted from the significance test due to their low representation in terms of implant years.

5.2.4. Rate of Ruptures vs. Device Size for the Textured Device in the R/A Subpopulation

Table 5.2.4 shows the estimates of rate of rupture per 10,000 implant years for the smooth device, by device size category.

Table 5.2.4. Rate of Rupture (RR) per 10,000 Implant Years for Textured Device in the R/A Subpopulation, by **Device Size Category**

Device Size Category	Total Implant Years	Total Ruptures	RR	std. err.
1: <= 300 cc	90,768.7	19	2.09	0.48
2: 300 – 375 cc	61,164.2	9	1.47	0.49
3: 375 – 500 cc	53,354.0	10	1.87	0.59
4: > 500 cc	22,071.1	9	4.08	1.35
Missing	15,557.0	2	1.29	0.90

Note: There is no significant difference in RR across the Device Size categories, including (p=.42) or not including (p=.32) the Missing category.

6. RESULTS FOR THE TOTAL RECONSTRUCTION SUB-POPULATION

This sub-population consists of all implants placed for either revision reconstruction or primary reconstruction.

6.1. Rate of Ruptures vs. Surgical Approach in Total Reconstruction Subpopulation

Table 6.1. Rate of Rupture (RR) per 10,000 Implant Years in T/R Subpopulation by **Surgical Approach**

Approach	Total Implant Years	Total Ruptures	RR	std. err.
Inframammary	57,963.9	18	3.11	0.73
Periareolar	18,234.1	3	1.65	0.95
Scar	4,984.0	0	0.00	0.00
Transaxillary	4,404.7	1	2.27	2.27
Other	66,111.3	28	4.24	0.80
Missing	4,289.9	4	9.32	4.66

Note: Omitting the 'Scar', 'Other' and 'missing' levels due to low total implant years, there is no significant difference in RR across the remaining Surgical Approaches (p=.47). When the 'Trans' level is also excluded, there is no significant difference between Inframammary and Periareolar (p=.22).

6.2. Rate of Ruptures vs. Device Placement in the T/R Subpopulation

Table 6.2 shows the estimates of rate of rupture per 10,000 implant years, by device placement, in the T/R subpopulation.

Table 6.2. Rate of Rupture (RR) per 10,000 Implant Years in the T/R Subpopulation, by **Device Placement**

Placement	Total Implant Years	Total Ruptures	RR	std. err.
Sub-glandular	26,471.4	9	3.40	1.13
Sub-muscular	122,395.6	39	3.19	0.51
Other	3,349.3	3	8.96	5.17
Missing	3,771.7	3	7.96	4.59

Note: There is no significant difference in RR across all categories (p=.52). Also, the difference between Sub-glandular and Sub-muscular is not significant (p=.86).

6.3. Rate of Ruptures vs. Incision Size in the T/R Subpopulation

Table 6.3 shows the estimates of rate of rupture per 10,000 implant years, by incision size, in the R/A subpopulation.

Table 6.3. Rate of Rupture (RR) per 10,000 Implant Years in the T/R Subpopulation, by **Incision Size**

Incision Size	Total Implant Years	Total Ruptures	RR	std. err.
Small (0-3 cm)	12,138.6	2	1.65	1.17
Medium (3-6 cm)	94,833.2	35	3.69	0.62
Large (6-9 cm)	46,138.2	17	3.68	0.89
Extra Large (>9 cm)	139.6	0	0.00	0.00
Missing	2,738.4	0	0.00	0.00

Note: There is no significant difference in RR across the Incision Sizes (p=.28). Size Categories 'Extra Large' and 'Missing' were omitted from the significance test due to their low representation in terms of implant years.

6.4. Rate of Ruptures vs. Device Size in the T/R Subpopulation

Table 6.4 shows results for device size in the T/R subpopulation.

Table 6.4. Rate of Rupture (RR) per 10,000 Implant Years in the T/R Subpopulation, by **Device Size Category**

Device Size Category	Total Implant Years	Total Ruptures	RR	std. err.
1: <= 300 cc	33,509.8	10	2.98	0.94
2: 300 – 375 cc	22,592.0	4	1.77	0.88
3: 375 – 500 cc	33,645.1	14	4.16	1.11
4: > 500 cc	21,739.1	7	3.22	1.22
Missing	11,828.6	6	5.07	2.07

Note: There are no significant differences in RR across these categories (p=.40). If the 'Missing' category is excluded, then p=.39.

6.5. Rate of Ruptures vs. Surface Characteristics (Smooth or Textured) in the T/R Subpopulation

Table 6.5 shows the estimates of rate of rupture per 10,000 implant years by Surface Characteristics, for the T/R subpopulation..

Table 6.5. Rate of Rupture (RR) per 10,000 Implant Years in the T/R Subpopulation, by **Surface Characteristics**

Surface Characteristics	Total Implant Years	Total Ruptures	RR	std. err.
Smooth	25,419.9	11	4.33	1.30
Textured	123,314.5	41	3.32	0.52
Missing	7,253.6	2	2.76	1.95

Note: There is no significant difference in RR across the three categories (p= .73). Also, there is no significant difference in RR between Smooth and Textured devices (p=.48).

CURRICULUM VITAE, Doyle L. Hawkins, Ph. D.

September 18, 2003

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EDUCATION

Ph.D. Biostatistics, Minor in Operations Research
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Ph. D. Dissertation: Sequential Detection Procedures for Autoregressive Processes
Research Advisor:

M.S. Statistics, Texas A&M University, December

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PROFESSIONAL EXPERIENCE

Administration

Associate Chair, Mathematics Department, University of Texas at Arlington.

Teaching

- Present **Associate Professor**, Mathematics Department, University of Texas at Arlington. Teach graduate courses in mathematical statistics, regression analysis, linear models, nonparametric theory, categorical data, and time series analysis (time and frequency domain); undergraduate courses in mathematical statistics, regression, and statistical methods.

Assistant Professor, Mathematics Department, University of Texas at Arlington

Visiting Assistant Professor and **Director** of Statistical Consulting Center in the Department of Statistics and Actuarial

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Consulting

Clinical trial analysis for

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Haag Engineering Company, 2455 McIver Rd., Dallas, TX 75006. Developed
Logistic models for hail damage analyses in roofing material experiments. Developed estimates of hail frequency in
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Johnson and Johnson Medical, Inc.,
Duties included design and protocol review of clinical trials for wound care products, design and analysis of pre-clinical studies, power calculations, software support.

U.S. Public Health Service/Region VI. Performed statistical assessment of efficacy of ventilation fans in toll booths in El Paso, Texas border control stations. (Contact:

Director, Statistical Consulting Center in the Department of Statistics and Actuarial Science at the University of Iowa.

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ACADEMIC EXPERIENCE

Teaching: Mathematical statistics, linear models, large sample theory, nonparametrics, time series, categorical data analysis, generalized linear models.

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26. Han, C. P. and Hawkins, D. L. [illegible] A smooth adaptive estimator of the mean of a symmetric or asymmetric distribution. Communications in Statistics, Theory and Methods 23, 1-10.

27. Hawkins, D. L. and Kochar, S [illegible] Inference about the change-point in a NBUE-NWUE model. *Sankhya,* 59, 117-132.

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1. Hawkins, D. L. and McNeil, R. The effects of a client's age and disability upon the employment preferences of therapeutic recreation majors. Department of Statistics and Actuarial Science Technical Report Series, University of Iowa. Work done under the auspices of the Statistical Consulting Center.

2. Hawkins, D. L. and Kochar, S.C. Inference for the crossing point of two continuous cdf's. Technical report #179, Department of Statistics and Actuarial Science, University of Iowa.

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4. Hawkins, D. L., Han, C.-P. and Eisenfeld, J. Estimating transition probabilities from aggregate samples augmented by haphazard repeats. Technical Report #302, Department of Mathematics, University of Texas at Arlington.

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PAPERS IN PREPARATION

1. [illegible]

2. [illegible]

PRESENTATIONS

1. Applications of the Cumulative Sum Statistic in controlled clinical trials. Presented at the national meeting of the Society of Controlled Clinical Trials, San Francisco, California,

2. A simple least squares method for estimating a change in mean. Presented at the national meetings of the American Statistical Society, Las Vegas, Nevada, August

3. Retrospective and sequential tests for shifts in linear models with time series regressors and errors. Presented at Joint Statistical Meetings in New Orleans, Louisiana, August

4. With McNeil, R., Barber, E., and Winslow, R., The effect of a client's age upon the employment preferences of therapeutic recreation majors. Presented at the Society of Park and Recreation Educator's Leisure Research Symposium, San Antonio, Texas, October.

5. A Gateaux-scores test of equality versus crossing hazards of two survival distributions. Presented as an invited talk at the Department of Biostatistics, University of North Carolina, May.

6. A Gateaux-scores test of equality versus crossing hazards of two survival distributions. Presented to Department of Statistics, Texas A & M University, December

7. Estimating transition probabilities from aggregate samples augmented by haphazard recaptures. Presented to Stephen F. Austin State University, March

8. Estimating transition probabilities from aggregate samples plus partial transition data. Presented at the meeting of the Bernoulli Society in Calcutta, India, Januar

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